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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---------------------------|---------------------------------------|-------------------------------|---------------------|------------------|
| 10/800,169 | 03/10/2004 | Shlomo Ben-Haim IMP031-228870 | | 9051 |
| | 7590 05/18/2007 K, SHORR AND SOLIS | EXAMINER | | |
| 250 PARK AV | • | LAYNO, CARL HERNANDZ | | |
| 10TH FLOOR NEW YORK, N | NY 10177 | ART UNIT | PAPER NUMBER | |
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| | | | MAIL DATE | DELIVERY MODE |
| • | | | 05/18/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | Application N | lo. | Applicant(s) | | | | |
|--|--|----------------------|---------------|---------------------|--------------------|-------------|--|--|--|
| Office Action Summary | | 10/800,169 | | BEN-HAIM ET AL | | | | | |
| | | Examiner | • | Art Unit | 100 000 000 | | | | |
| | | | Carl H. Layno | | 3766 | | | | |
| | The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | | | | |
| Status | · | | | · | | | | | |
| 1)⊠ | Responsive to communication(s) file | ed on 26 Fel | bruarv 2007. | | | • | | | |
| | This action is FINAL . 2b) ☐ This action is non-final. | | | | | | | | |
| ′== | Since this application is in condition | • | | | secution as to the | e merits is | | | |
| 7,— | closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | | | | |
| Disposition of Claims | | | | | | | | | |
| 4)⊠ | 4)⊠ Claim(s) <u>1 and 28-47</u> is/are pending in the application. | | | | | | | | |
| | 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | | | |
| | 5) Claim(s) is/are allowed. | | | | | | | | |
| 6)⊠ | Claim(s) 1,38,39 and 45-47 is/are re | ejected. | | | | | | | |
| 7)🖂 | Claim(s) 28-37 and 40-44 is/are obj | ected to. | | | | | | | |
| 8)□ | Claim(s) are subject to restrict | ction and/or | election requ | irement. | | | | | |
| Applicati | on Papers | | | | | | | | |
| 9) 🗌 | The specification is objected to by th | e Examiner. | • | | | | | | |
| 10)🖂 | The drawing(s) filed on 21 August 20 | <u>006</u> is/are: a | a)⊠ accepted | d or b)□ objected t | o by the Examine | er. | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | | | | |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | | | | |
| Priority u | ınder 35 U.S.C. § 119 | | | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: | | | | | | | | | |
| | 1. ☐ Certified copies of the priority documents have been received. 2. ☒ Certified copies of the priority documents have been received in Application No. 09/831,100. | | | | | | | | |
| 3. ☐ Copies of the certified copies of the priority documents have been received in Application No. <u>09/03 1, 100.</u> | | | | | | | | | |
| application from the International Bureau (PCT Rule 17.2(a)). | | | | | | | | | |
| * See the attached detailed Office action for a list of the certified copies not received. | | | | | | | | | |
| | | | | | | | | | |
| Attachment(s) | | | | | | | | | |
| 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) | | | | | | | | | |
| | e of Draftsperson's Patent Drawing Review (I | PTO-948) | 5) | Paper No(s)/Mail Da | | | | | |
| 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 2/7/07,11/7/06. 5) Notice of Informal Patent Application 6) Other: | | | | | | | | | |

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DETAILED ACTION

1. Acknowledgment is made of applicant's amendment, which was received by the Office on February 26, 2007.

2. Claims 2-27 are canceled. Claims 32-47 have been added. Claims 1 and 28-47 are active.

Information Disclosure Statement

3. Acknowledgment is made of applicant's Information Disclosure Statements (PTO-1449s), which were received by the Office on November 7, 2006 and February 7, 2007.

Double Patenting/Terminal Disclaimer

4. Acknowledgment is made of applicant's Terminal Disclaimer, which was received by the Office on February 26, 2007. This Terminal Disclaimer has been APPROVED. Consequently, the Examiner is withdrawing the 35 USC 101 non-statutory obviousness type double patenting rejection that was made against claim 1 in the last Office Action.

Claim Rejections - 35 USC § 112

5. In view of applicant's modifications to the claim 30, the Examiner is withdrawing the 35 U.S.C 112 rejections, which were made against claims 30 and 31 in the last Office action.

Claim Rejections - 35 USC § 102

6. Applicant's arguments, see "REMARKS", filed 2/26/2007, with respect to the rejection(s) of claim(s) 1 and 28 under Darvish et al (US 6,292,693) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Shemer et al (US 2004/0138710).

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- 8. Claims 1, 38, 39, 45, and 46 are rejected under 35 U.S.C. 102(e) as being anticipated by Shemer et al (US 2004/0138710).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131. The Examiner notes that the earliest filing date of the Shemer et al reference is September 16, 1996.

In regard to claims 1 and 39, the Shemer et al (US 2004/0138710) patent application publication describes a method and apparatus (Fig.2) including a plurality of sensors **70,72**, stimulation electrodes **98**, and a control unit **90**, which includes devices **80** and **86** for analyzing

sensor signals and based upon these, generates a stimulation signal, respectively. Sensors **70,72** may physiological sensors (p.2, paragraph [0012], lines 6-7) and send "physiological –sensor signals" to the control unit **90** (col.2, paragraph [0012], line 9). These sensed signals "serve as feedback to enable the control unit to iteratively adjust the ETC signal applied to the septum" (col.2, paragraph [0012], lines 9-11) via electrodes **98,65,69,165,167,169,265,267,269,271** (Figs.1A, 1B, 1C, and 2).

In regard to claim 38, the sensors of Shemer et al may include "motion sensors". See p.2 paragraph [0012], line 3.

In regard to claim 45, the at least one sensor of Shemer et al may include an accelerometer 70 (Fig.1A). See p.3, paragraph [0032], line 9.

In regard to claim 46, the at least one sensor of Shemer et al may include a sensing electrode (p.2, paragraph [0012], line 14).

Claim Rejections - 35 USC § 103

- 9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 10. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 - 1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.

- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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11. Claim 47 is rejected under 35 U.S.C. 103(a) as being obvious over Shemer et al (US 2004/0138710) in view of Alt (US 4,884,576).

The applied reference has a common inventor with the instant application, Itsik Shemer. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(1)(1) and § 706.02(1)(2). Unlike applicant's claimed device, the Shemer et al reference teaches the use of separate stimulation electrodes 98 (Fig.2) and sensing electrodes 74, rather than electrodes that both sense and stimulate.

To have specified a dual purpose stimulate/sense electrode for use within the heart would have been an obvious selection to one of ordinary skill since the use of dual purpose pace/sense

electrodes is an old and well known feature in implantable pacemakers, as exemplified by the dual purpose pace/sense electrode 6 of Alt (US 4,884,576) (Fig.2).

Allowable Subject Matter

12. Claims 28-37 and 40-44 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

13. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carl H. Layno whose telephone number is (571) 272-4949. The examiner can normally be reached on 9/4/5.

If attempts to reach the examiner by telephone are unsuccessful, the a voice message may be left on the examiner's telephone answering machine or an e-mail may be sent to carl.layno@uspto.gov. Alternatively, a fax message may be sent. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CARL LAYNO

Carl H. Lagro

CHL 5/13/2007